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Section 5:

510(k) Summary

21 CFR 807.92

JUL 3 2008

1. Submitted by:

Submitter's Name	Signal Medical Corporation
Address:	1000 Des Peres Road, Suite 140 St. Louis, MO 63131 P: 314-775-0518 F: 314-775-0524
Establishment Registration#:	1932213
Correspondent:	Brian Katerberg; Leo Whiteside, MD; Louis Serafin, MD
Date:	March 4, 2011

2. Device Name:

Trade Name:	Symmetric™ Total Knee System
Proprietary Name:	Signal Medical Corp. Symmetric™ Total Knee System
Common Name:	Knee Prosthesis
Classification Name:	- Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, metal/polymer (888.3560 - JWH)

3. Device Class

Regulatory Class:	Class II
Product Code:	JWH
Panel:	Orthopedic
Regulation Number:	21 CFR 888.3560

4. Predicate Device: Beacon Cemented and Uncemented Total Knee System (K051510), Profix Total Knee System (K933958) Similarities to these components are based on design, indications for use, and materials.

Predicate Device Comparison

	Category	Symmetric Total Knee System	Beacon Cemented and Uncemented Total Knee System	Profix Total Knee System
	510K #	K080199	K051510	K933958
	Fixation Method	Cemented	Cemented/less	Cemented
Femoral	Width (mm)	50-86mm	58-82mm	Similar
	Substrate Material	CoCr	CoCr	CoCr
	Coating	Ti Plasma Spray	Sintered Beads	Sintered Beads
Tibial Tray	ML-Width	49-84mm	63-88mm	Similar
	Substrate Material	Titanium 6Al-4V	Titanium 6Al-4V	Titanium 6Al-4V
	Coating	Ti Plasma Spray	Sintered Beads	Sintered Beads
Tibial Poly	Thickness w/ tray	10-35mm	10-20mm	Similar
	Standard/Deep	Standard/Deep	Standard/Deep	Standard/Deep
	Material	UHMWPE	UHMWPE	UHMWPE
Metap-hyseal Stem	Diameters	18-24mm	NA	Similar
	Lengths	50-63mm	NA	Similar
	Attachment Method	Morse Taper	NA	Morse Taper
	Material	Titanium 6Al-4V	NA	Titanium 6Al-4V
Revision Stem	Diameters	10-26mm	NA	Similar
	Lengths	100 - 200mm	NA	Similar
	Fixation Method	Morse Taper	NA	Morse Taper
	Material	Titanium 6Al-4V	NA	Titanium 6Al-4V
Patella	Disk Diameter	25 - 40mm	26 - 41mm	Similar
	Material	UHMWPE	UHMWPE	UHMWPE
	Intended Use	Cemented	Cemented	Cemented

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5. Device Description:
The Symmetric™ Total Knee System is intended for the resurfacing of the knee joint. The system consists of metallic femoral and tibial components (including an available metaphyseal stem) and a polyethylene tibial insert and patellar component.

The FEMORAL COMPONENT is designed for left/right orientations. The femoral component is manufactured from cast cobalt chromium/molybdenum (CoCrMo). The femoral component will be available in eight sizes (1-8) and will have a central post (with a 5° valgus angle) and gussets to aid in rotational stability and to increase strength. It will be plasma sprayed with Commercially Pure Titanium (CPTi).

The TIBIAL TRAY is a symmetrically designed component, eliminating the need for left/right orientations. The tibial component is manufactured from wrought titanium alloy (Ti 6Al-4V). The tibial tray features a central post, a pair of gussets, and 2 to 4 pegs on the underside providing rotational stabilization and increased tray strength. Four screw holes in the tibial tray allow for optional screw fixation. The tibial tray is designed with locking features permitting the UHMWPE tibial insert to be snapped into place. The tibial tray has 8 sizes (1-8) and is plasma sprayed with Commercially Pure Titanium (CPTi).

The TIBIAL INSERT is also a symmetrically designed component manufactured from Ultra-High Molecular Weight Polyethylene (ASTM F648). The inserts' articulating geometry is semi-constrained and is captured in the tibial tray by the mating capture features. The insert is available in nine thicknesses (10, 12, 14, 16, 18, 20, 25, 30, 35mm) and 8 sizes (1-8).

The METAPHYSEAL STEM is designed to be driven onto a tibial tray further increasing the fit and fill of the component allowing for a more stable system.

The REVISION STEM is designed to be driven onto a tibial tray or femoral component further increasing the stability of a revision component.

The PATELLAR COMPONENT is dome shaped and tracks nicely against the femoral component.

6. Device Intended Use:
The Symmetric™ Total Knee System consist of single use components intended for total knee arthroplasty with the following indications.

1. Osteoarthritis (for cemented use only)
2. Rheumatoid Arthritis (for cemented use only)
3. Traumatic Arthritis (for cemented use only)
4. Where the use of a more conservative procedure has failed or is unacceptable.

7. Performance Summary:
Non-Clinical Testing:
-Testing performed was consistent with Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented

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Prostheses; Guidance for Industry and FDA (dated January 16, 2003). Tests included poly push in, push off, and pull out; tibial tray and femoral fatigue; femoral-tibial and femoral-patellar joint stability; femoral-tibial and femoral-patellar contact area/contact stress; static tensile and torsional testing of the modular stem/trunnion junction; and fatigue testing of the modular stems in conjunction with both the femur and tibia.

Clinical Testing:
No clinical data was utilized for the basis of substantial equivalence.

Conclusions:
Based on the Symmetric Total Knee System having the same intended use, the results of the non-clinical tests being substantially equivalent to or better than those of at least one predicate device, and the indications for use being similar, we feel that there are no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 11 2011

Signal Medical Corporation
% Mr. Brian Katerberg
Engineer
1000 Des Peres Road, Suite 140
Saint Louis, Missouri 63131

Re: K080199
Trade/Device Name: Symmetric Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: July 01, 2008
Received: July 03, 2008

Dear Mr. Katerberg:

This letter corrects our substantially equivalent letter of July 03, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other

requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4:

Indications for Use

510K Number: K080199

Device Name: Symmetric™ Total Knee Augments

Indications For Use:

The Symmetric™ Total Knee System consist of single use components intended for total knee arthroplasty with the following indications.

1. Osteoarthritis (for cemented use only)
2. Rheumatoid Arthritis (for cemented use only)
3. Traumatic Arthritis (for cemented use only)
4. Where the use of a more conservative procedure has failed or is unacceptable.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
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Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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